

### **REMARKS**

This submission is responsive to the Office Action dated September 18, 2008. Claims 1-7, 9-17 and 24-32 remain pending; of these, claims 13 and 14 are currently withdrawn.

#### **Claim Rejection Under 35 U.S.C. § 112**

In the Final Office Action, the Examiner rejected claims 12 and 27 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement and the enablement requirement. Applicant respectfully traverses this rejection.

Written description of the feature of placing an IMD within a recess is provided by, e.g., paragraph [0051] of Applicant's specification as filed. The Office Action argues that this is an alternative method of implantation. However, the context of paragraph [0051] of Applicant's specification as filed provides support for the combination of placing an IMD within a pocket and a recess. As stated in paragraph [0046] of Applicant's specification as filed, "In some cases, implantation of an IMD may include an extra surgical stage." Following a discussion of the use of a dummy IMD in paragraphs [0046]-[0050], paragraph [0051] states in part, "In addition, the surgeon may in some cases determine that the skull of the patient may be prepared to receive the IMD. The surgeon may, for example, create one or more troughs or recesses in the skull of the patient to receive the IMD or one or more modules thereof." (Emphasis added.) Clearly, in this context, Applicant's specification discloses the combination of a recess and a pocket.

In addition, the combination of placing a device in a recess and a pocket is enabled by Applicant's specification as filed. For example, one of ordinary skill in the art would have understood that creation of a recess in a pocket could be accomplished using common surgical tools such as a bone chisel or a rotary bit. In the event the Examiner maintains this rejection, Applicant respectfully requests the Examiner provide additional explanation as to how one of ordinary skill in the art would be unable to make and use Applicant's invention as recited in claims 12 and 27.

Claims 12 and 27 recite subject matter included in the present application as originally filed and enabled by the present application as originally filed. For this reason, Applicant requests immediate withdrawal of each of the rejections under 35 U.S.C. §112.

**Claim Rejections Under 35 U.S.C. § 103**

The Office Action rejected claims 1-7, 9-12, 15-17 and 24-32 as being unpatentable over U.S. Pat. No. 6,427,086 to Fischell et al. (hereinafter “Fischell”) in view of U.S. Pat. No. 6,648,914 to Berrang et al. (hereinafter “Berrang”) and U.S. Pub. No. 2003/0109903 Berrang et al. (hereinafter “Berrang Application”) under 35 U.S.C. §103(a). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant’s claims, and would not have suggested a rational reason to arrive at the claimed invention.

***Claims 1-7, 9-12, 15-17, 24, 25, 30 and 31***

In the rejection of independent claim 1, the Examiner cited Fischell as disclosing implanting a low profile medical device between the scalp and the cranium at the top of the head. The Examiner also found that Fischell discloses that the device may comprise a neurostimulator with brain leads, may be secured via bone screws, and may be implanted in a recess. The Examiner correctly found that Fischell fails to disclose implantation steps recited in Applicant’s claims as well as specific dimensions of the device recited in Applicant’s claims 2-6, but stated that the combined disclosures of Berrang and Berrang Application would have made such features obvious to one of ordinary skill in the art at the time of Applicant’s invention. Applicant disagrees with the Examiner’s analysis as the Office Action fails to account for each of the features recited in the claims.

Claim 1 recites, in part, placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp; drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull; and inserting one or more leads through the burr holes and into a brain of the patient. The rejection failed to account for this combination features. For this reason alone, the Examiner failed to provide a *prima facie* case of obviousness with respect to claim 1.

In addition, the features recited in claim 1 would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention. For example, neither Fischell, Berrang nor Berrang Application teaches or suggests drilling a burr hole in a portion of a skull under a scalp flap that is also used to implant a low-profile medical device. In contrast, Fischell teaches wires are *tunneled under the scalp* to burr holes, e.g., as shown in FIGS. 15 and 16 and described in column 29, lines 21-48.

Berrang and Berrang Application also fail to disclose the features of drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, and inserting one or more leads through the one or more burr holes and into the brain. Berrang and Berrang Application disclose techniques for a cochlear implant. The drilling disclosed by Berrang is used to implant a microphone in posterior wall of the external auditory canal of a patient.<sup>1</sup> The cochlear implants disclosed by Berrang and Berrang Application have no use for drilling a burr hole in the skull of a patient, much less for drilling a burr hole in a portion of the skull of the patient exposed by separating a scalp flap from the skull, and inserting a lead through the hole and into the brain.

Fischell, Berrang and Berrang Application also fail to disclose or suggest a pocket adjacent to the fold and between the scalp and the skull, or placing at least a portion of a low-profile implantable medical device in the pocket as recited by claim 1. In fact, neither Fischell, Berrang nor Berrang Application demonstrate that there is any separation whatsoever between a scalp and skull behind as fold a recited in claim 1. While the Office Action acknowledged that Fischell fails to disclose implantation steps recited in Applicant's claims, Berrang and Berrang Application fail to provide a rational reason to create a pocket as recited in claim 1.

For example, in contrast to claim 1, Berrang illustrates in FIG. 3 that the implant is placed in front of the fold. Further, Berrang teaches that line 34 (FIG. 3) illustrates an incision whereby a surgeon raises a postauricular flap to facilitate the implantation.<sup>2</sup> Berrang teaches raising the postauricular flap, and placing the device beneath the flap, on the "flap" side of the fold. Berrang in no way suggests the additional step, after raising the flap, of creating a pocket adjacent to the fold and between the scalp and the skull. Because Berrang does not disclose creating a pocket,

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<sup>1</sup> Berrang, column 14, lines 52-59.

<sup>2</sup> Berrang, column 13, lines 40-53.

Berrang also does not disclose placing at least a portion of the low-profile implantable medical device in the pocket.

Similarly, Berrang Application also fails to teach or suggest such a feature. For example, as shown in FIG. 3 of Berrang Application, the implant is placed in front the fold. Further, Berrang Application teaches that skin flap 23 is pulled back to facilitate implantation.<sup>3</sup>

Because the Examiner has failed to provide a rational reason one of ordinary skill in the art would have found the features of a pocket, placing at least a portion a low-profile implantable medical device in the pocket, drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, or inserting one or more leads through the one or more burr holes and into the brain as recited by claim 1, the Examiner has failed to provide a *prima facie* case of obviousness as required to maintain the rejection under 35 U.S.C. §103(a). For at least the same reasons, dependent claims 2-7, 9-12, 15-17, 24, 25, 30 and 31 would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention. The dependent claims also recite additional features not taught or suggested by the cited references.

As an example, with respect to claim 12, the cited references fail to disclose creating a recess in the skull in combination with the features of claim 1, including the creation of a pocket adjacent to the fold and between the scalp and the skull.

As another example, claim 25 recites placing all of the low-profile implantable medical device in the pocket. The Office Action fails to account for this feature in the rejection. In the event the Examiner maintains the rejection, Applicant respectfully requests the Examiner explain with specificity how one of ordinary skill in the art would have found such a feature to be obvious.

For at least these reasons, the subject matter of Applicant's claims 1-7, 9-12, 15-17, 24, 25, 30 and 31 not have been obvious to one of ordinary skill in the art at the time of Applicant's invention as required to maintain the rejection under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

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<sup>3</sup> Berrang Application, paragraph [0056].

***Claims 26 and 27***

Independent claim 26 recites placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. As discussed with respect to claim 25 above, one of ordinary skill in the art would not have had a rational reason to include such a feature in the system disclosed by Fischell. For example, the Office Action fails to account for this feature in the rejection. In the event the Examiner maintains the rejection, Applicant respectfully requests the Examiner explain with specificity how one of ordinary skill in the art would have found such a feature to be obvious. Claim 27 is patentable for at least the reasons claim 26 is patentable.

For at least these reasons, the subject matter of Applicant's claims 26 and 27 not have been obvious to one of ordinary skill in the art at the time of Applicant's invention as required to maintain the rejection under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

***Claims 28, 29 and 32***

Independent claim 28 recites placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. As discussed with respect to independent claim 1, one of ordinary skill in the art would not have had a rational reason to include such a feature in the system disclosed by Fischell. For example, the Office Action fails to account for this feature in the rejection. In the event the Examiner maintains the rejection, Applicant respectfully requests the Examiner explain with specificity how one of ordinary skill in the art would have found such a feature to be obvious. Claims 29 and 32 are patentable for at least the reasons claim 28 is patentable.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of Applicant's claims 28, 29 and 32 under 35 U.S.C. §103(a). Withdrawal of this rejection is requested.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant does not acquiesce with any of the Examiner's current rejections or characterizations of the prior art, and reserve the right to further address such rejections and/or characterizations.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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